Pharmacist-Provided Self-Administered Contraception Frequently Asked Questions

Is access to birth control without meeting with a doctor safe?

There is substantial scientific research showing that over-the-counter (OTC) access to oral contraceptives is safe. The American Congress of Obstetricians and Gynecologists (ACOG), the preeminent authority on women's health issues, officially endorsed making oral hormonal contraceptives available OTC in 2012 and reaffirmed their decision in 2014. They found that women were able to self-screen for contraindications as well or better than physicians, making a doctor's appointment an unnecessary obstacle for most women.

A study done by the National Institute of Health (NIH) confirmed ACOG's opinion and found that woman were able to accurately self-assess for OTC birth control.² NIH also references several other studies that affirm the safety of OTC birth control, including a 2008 study in Washington state³:

"In a recent study from Washington state, Shotorbani et al. demonstrated that women's responses to a medical eligibility checklist for hormonal contraceptives was just as accurate as a provider's formal evaluation."

NIH noted that where women and physicians disagreed in their assessments, women were more likely to report potential adverse effects. There was a statistically insignificant number of women that missed potential complications during the self-assessment that would have been detected during a medical evaluation.

In addition, strict protocols – similar to those currently used for immunizations – have been developed to ensure that the pharmacists are safely dispensing oral hormonal birth control pills. If there are any concerns, or if a woman feels unable to self-screen, the pharmacist will refer them to their primary care physicians.

The academic research has shown widespread consensus that OTC birth control is safe and women are able to effectively self-screen and understand contraindications. Through the protocols and the ability of women to self-screen, there are adequate layers of safeguards in place for pharmacists to safely prescribe birth control pills.

¹ http://www.acog.org/Resources-And-Publications/Committee-Opinions/Committee-on-Gynecologic-Practice/Over-the-Counter-Access-to-Oral-Contraceptives

² http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2615461/pdf/nihms-82574.pdf

 $^{^3\}underline{http://www.ncbi.nlm.nih.gov/pubmed/?term=Shotorbani+S\%2C+Miller+L\%2C+Blough+DK\%2C+Gardner+J.}\\ +\underline{Agreement+between+women's+and+providers'+assessment}$

Will contraceptives still be covered by insurance?

Generally, all insurers cover prescribed preventive contraceptives for women. Senate Bill 16-135, signed into law in Colorado in June 2016, allows pharmacists to practice under Statewide Protocols. One of the first protocols allows pharmacists who have completed additional training to prescribe birth control, which is billed to insurance like any other prescription.

Why not make other forms of contraception available via statewide protocols?

Most research has focused on self-administered hormonal contraceptives. If sufficient evidence develops that shows other forms are appropriate for pharmacist statewide protocol access, future legislation could include alternative forms. In fact, other states are exploring expanding to injectables and rings.

Are pharmacists able to prescribe other medications?

Pharmacists have the ability to provide immunizations consistent with CDC guidelines. The benefits of vaccine availability at pharmacies are well documented and proven. Pharmacists interested in administering vaccines must complete training to be certified, and then are authorized to prescribe vaccines.

What other contraceptive options are available at the pharmacy?

Emergency contraceptives and condoms are already available. This initiative ensures that women have access to additional, very effective, preventive options as well.

How will this proposal impact women's health?

This represents an unprecedented expansion of access to birth control. Colorado will be the third state in the nation to offer this initiative, following Oregon and California.

Unintended pregnancies are the source of financial and physical stress for many women. Research has shown that unintended pregnancies are more likely to result in health complications for both the child and mother, and results in costing both the patient and healthcare system more money. Research at the University of California, San Francisco, estimated that unintended pregnancies could be reduced by up to 25% if oral hormonal birth control was made available OTC.

As part of the protocol, pharmacists must counsel women on the importance of routine health screenings and STD prevention, and encourage regular visits to a primary care provider. A pharmacist may not also continue to prescribe oral contraceptives for more than three years without evidence of a visit to a physician or primary care provider.

Why does this apply to women 18 years of age and older?

There are several studies that have demonstrated the safety and effectiveness of over the counter hormonal contraceptives. Unfortunately, these studies involved women over 18 years of age. This initiative will not change the current methods of obtaining birth control for adolescents; they could still see a doctor at any age to get a prescription for oral contraceptives or purchase emergency contraceptives directly from the pharmacy. It will not create any additional limitations.

Furthermore, the American Academy of Pediatrics (APP) recommends that adolescents consult with their doctors and work through these questions in a secure environment. The AAP position is that the preferred method of contraception for adolescents is not oral contraceptives, but rather long-acting reversible contraception such as IUDs and progestin implants. According to their review, these alternative contraceptives are much more effective and safe for adolescents. An initial clinical visit with a medical provider will allow adolescents to review these options.

What is the medical liability for prescribing pharmacists?

Per SB 16-135, pharmacists must possess professional liability insurance. In many cases, their employer provides liability insurance. Pharmacists often carry their own individual policy. This has already been in place and further clarified in statute

What is the notification process for the patient's primary care doctor?

Pharmacists must notify the patient's primary care provider upon prescribing a contraceptive agent. The notification may occur via a shared medical record, fax, phone call, or other mechanism. If no primary care doctor is identified, pharmacists must provide the patient with a visit summary to share with subsequent primary care interactions.

What about moral and ethical exemptions for pharmacists?

Pharmacists are not forced by statute to prescribe contraceptive agents when they have a moral or ethical objection. Similar to any prescription that may be objectionable to an individual pharmacist, individuals will be encourage to refer the patient to another pharmacy or pharmacist that provides that service.

Does the Colorado medical community support this concept?

The hormonal contraceptive protocol was developed collaboratively by the Colorado Department of Public Health and Environment, the Colorado Board of Medicine, the Colorado Board of Nursing, and the Colorado Board of Pharmacy.